



TELEMEDICINE IN EYE AND CONTACT LENS CARE



Ensuring patient health and safety
in the evolving digital health landscape.

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Doctors of optometry provide the majority of contact lens care in the United States. This article reviews certain aspects of telemedicine and online eye care that optometrists and their teams should be aware of in 2021 to help ensure optimal population health outcomes and patient safety.

TELEHEALTH AND TELEMEDICINE

Telehealth is defined as “the use of electronic information and telecommunications technologies to support long-distance clinical health

care, patient and professional health-related education, public health, and health administration.”¹

Telehealth is a constantly evolving toolbox that has seen many of its components fast-tracked as a result of the COVID-19 pandemic. The American Optometric Association (AOA) recently revised its 2020 position statement on telemedicine in optometry, recognizing these rapid changes and further defining telemedicine in optometry as “the provision of eye, adnexa, visual system, and related systemic health care services (collectively ‘eye, health,

and vision services’). Asynchronous and synchronous technologies can be used to provide this type of care, including videoconferencing, internet-based services, store-and-forward imaging, streaming media, and terrestrial and wireless communications.”²

In this revision, what remains consistent with the AOA’s original statement is a focus on that which serves the best interests of patients—namely, that an in-person, comprehensive eye examination is the gold standard for health, and every optometrist has the responsibility to take an active role in the evolution and use of technology while taking into account compliance with laws and ethical obligations in clinical decision-making for patient care (see *Highlights of the AOA Statement*).

Optometrists share challenges with physician colleagues in family medicine, dentistry, and other primary health care fields in which technology cannot effectively meet standards for in-person care or replace essential aspects of primary care delivery. Evidence has shown the value of telemedicine in behavioral health, rehabilitation, patient counseling, and other downstream care delivery, but desired health outcomes remain dependent on primary evaluation, diagnosis, and treatment of patients and on policies that support an existing doctor-patient relationship.^{2,3} Emerging evidence reinforces to just

how important the role of the optometrist is in primary eye care delivery and treatment involving contact lenses.

THE HEALTH DANGERS OF APPS

My colleague Gregory Wolf, OD, MPH, and I recently presented initial findings from our clinical research regarding public facing eye-related smartphone applications (apps), including those involving contact lenses.^{4,5} Our investigation evaluated patient engagement with purported “online eye tests,” including those that aim to generate contact lens prescriptions. Systematically reviewing the app landscape, we identified 34 apps that are available in the United States, including contact lens-related apps that are heavily marketed directly to the public.

We found that, of the 34 apps, none follow standard of care when compared to evidence-based clinical guidelines.⁶ Of the contact lens-related apps investigated, none met the FDA’s criteria for “relatively harmless apps” or for “software as a medical device.” Throughout the course of our study, one app (Express Exam, from 1-800 Contacts) continued to offer a contact lens that was under FDA recall.

We also found little scientific accuracy, analytical validity, or reliability reflected in the final medical device outcomes generated by the apps. That is, almost every “new” contact lens prescription generated by an app was a duplicate of whatever contact lens specifications—usually from a picture of a contact lens box label—the user chose to upload at the beginning of the app process.

DECISION-MAKING AND SAFETY

Our findings regarding public understanding and use of the health apps were concerning. We found that 52% of research participants did not properly follow online app instructions. More than 82% of users of heavily marketed contact lens apps demonstrated multiple sources of confusion with the app process. In comparing their experience with apps to an eye examination,

HIGHLIGHTS OF THE AOA STATEMENT²

The AOA supports the appropriate use of telemedicine in optometry to access high-value, high-quality eye, health, and vision care. Telemedicine in optometry can serve to expand patient access to care, improve coordination of care, and enhance communication among all health care practitioners involved in the care of a patient.

The standard of care for eye, health, and vision services must remain the same regardless of whether services are provided in person, remotely via telehealth, or through any combination thereof. Doctors may not waive this obligation or require patients to waive their right to receive the standard of care.

The use of remote patient monitoring may be appropriate for data acquisition, patient communication, confirmation of expected therapeutic results, confirmation of stability or homeostasis, and assessing changes in previously diagnosed chronic conditions.

Use of direct-to-patient eye and vision health applications, including online vision tests and other mobile eye and vision-related applications, does not constitute telemedicine in optometry unless used under the direction of a doctor of optometry.

Fundamental elements of the doctor-patient relationship must be established and maintained. Physicians must act as advocates on behalf of the patient and are obligated to discuss necessary and appropriate treatment alternatives, and in good faith to fully inform the patient of all treatment options.

more than 96% of patients indicated confidence in their health-related decision-making following an in-person eye exam. By contrast, only 36% of those using an online app indicated confidence in their decision-making.

Practically speaking, how does this affect patient health? Compare it with other, non-eye-related medical online processes. For example, obtaining paid out-of-pocket prescription drugs (eg, for erectile dysfunction⁷) or medical devices customarily covered by medical insurance (eg, machines for continuous positive airway pressure therapy⁸) requires additional considerations, such as online professional consultations or established physician engagement for health insurance coverage. Similarly, pharmaceutical prescriptions can be

refilled and purchased online, but the physician (or licensed professionals under the physician’s supervision) and the patient-provider relationship are essential to this process.

Contact lenses are classified by the FDA as Class II and higher medical devices. Our findings demonstrated that investigated contact lens-related apps did not follow safe processes or approach the required standard of care delivered with in-person eye care. These app processes were primarily user-dependent and unlike other health care processes used to obtain medical devices. The app-based contact lens processes we reviewed did not safely adhere to FDA regulatory guidance or requirements for medical devices. The apps do not mirror national

evidence-based clinical standards or follow state regulatory language defining eye care or eye examination.⁶

When we participate in telemedicine, clinical decision-making requires us to be reasonable and prudent in serving the best interests of our patients. It also requires us to understand the legal risks involved and actions that may be construed as malpractice. In our investigation, we observed virtual doctors affiliated with the related app manufacturers or vendors appearing to sign off on app-driven prescriptions for contact lens replacement orders supplied directly from industry, without establishing virtual patient engagement as observed for other types of prescription treatments.⁷

As noted above, in all cases we documented, the contact lens prescription generated by an app was a duplicate of parameters from the packaging of a previously obtained contact lens prescription that the user was required to upload at the beginning of the app process. When that user input reflected eye- or vision-related findings indicating potential safety concerns (eg, decreased visual acuity), the contact lens prescription generated by the app was not altered from the original uploaded specifications.

App processes were observed to be fraught with myriad other problems. These included users uploading expired or inaccurate prescription information or experiencing confusion (eg, problems following instructions, inaccuracies in measurement of test distance). Further, in some cases, the vendor offered a substitute contact lens brand as a replacement, which is not allowed by the FDA. As noted above, we also observed a vendor offering a user a substitute contact lens that was under FDA recall.

Without apps that adhere to a process that ensures quality health care and safety standards, the public's eyesight and eye health are at risk. The take-home message is that optometrists, as majority providers of US contact lens care, are the public's primary health and

FIVE GUIDING PRINCIPLES OF THE APS

1. Support and advocate the doctor-patient relationship and ensure the delivery of quality care and health outcomes.
2. Support and advocate for the safest, healthiest, and most effective use of medical devices while promoting advancements in technology to create better patient health outcomes.
3. Support and advocate for the inviolability of a patient's prescription, determined through consultation between a patient and his or her doctor.
4. Support and advocate for needed enforcement and/or needed strengthening of patient health and safety laws and regulations.
5. Educate and inform policymakers, media, and the public about the importance of doctor-patient decision-making and respond to dangerous, abusive, or harmful medical device marketing practices that undermine quality care or that place patients at increased risk for harm.

safety physician advocates for the prevention of sight-threatening complications from risky industry-driven supply and use of contact lens medical devices.

MOVING EYE CARE SAFELY FORWARD

Optometrists must keep abreast of the evolving digital landscape and its interactions with eye care and population health. One important resource for doctors, staff, patients, industry, and other stakeholders is the Health Care Alliance for Patient Safety (APS). The APS was founded in 2018 to “advocate for patient safety and to protect and defend the doctor-patient relationship—the essential foundation of personalized health care decision making.”⁹ APS members from across the United States strive to raise awareness of issues and protect public health (see *Five Guiding Principles of the APS*).

We must also engage with local, state, and national professional health-related resources. The AOA undertakes ongoing advocacy with the FDA, the US Federal Trade Commission, members of Congress, and other regulatory and health care decision-making entities and stakeholders.¹⁰ Along with state AOA affiliate organizations, the AOA's leading

voice continues to fight for patient health and safety through advocacy for the high value to health of evidence-based comprehensive optometric eye and vision care. Becoming involved in these efforts is the best way to stay informed ■.

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